

Section C 510(k) Summary**510(K) Summary**

"This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92."

"The assigned 510(k) number is: K131826 "

Premarket Notification [510(k)] Summary**1.0 Submitter:**

Submitter's name : Jiangsu Toptouch Glove Co., Ltd.
Submitter's address : No.103 Xihu Road, Suqian, Jiangsu, 223800
China
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Name of contact person: Mr.Zhong Miao
Date of preparation : 2013-11-12

2.0 Name of the Device

Device Name: Powder Free Vinyl Patient Examination
Gloves, Clear (non-colored)
Proprietary/Trade name: Toptouch
Common Name: Exam gloves
Classification Name: Patient examination glove
Device Classification: I
Regulation Number: 21 CFR 880.6250
Panel: General Hospital (80)
Product Code: LYZ

3.0 Predicate device

Device Name: Powder-Free Vinyl Patient Examination Glove
(Non-colored)
Company name: Zhang Jia Gang Fengyuan Plastic Product Co.Ltd.
510(K) Number: K091663.

4.0 Device Description:**4.1 How the device functions:**

PVC films form a barrier to body fluids and bloodborne Pathogens

4.2 Scientific concepts that form the basis for the device

The PVC rubber is water tight under normal conditions of use. It's tensile properties cause it to conform to the hand, allowing movements necessary for a

medical procedure.

4.3 Physical and performance characteristics such as design, materials and physical properties:

Poly (vinyl chloride) glove is known to create a barrier to bloodborne pathogens and body fluids. ASTM conforming tensile properties create a glove that is strong and flexible. The leaching process removes traces of chemical accelerants that may be chemically irritating. The glove is manufactured in accordance with the requirements of ASTM D5250-06(Reapproved 2011) and ASTM D5151-06(Reapproved 2011) requirements.

5.0 Device Intended Use (Indication for use):

Powder Free Vinyl Patient Examination Gloves, Clear (non-colored) are disposable devices which made of PVC material ,intended for medical purpose that worn on examiner's hand or finger to prevent contamination between patient and examiner and they meets all of the requirements of ASTM standard D 5250-06 (Reapproved 2011).

Powder Free Vinyl Patient Examination Gloves, Clear (non-colored) is a disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.

6.0 Summary of the Technological Characteristics of the Device:

The Powder Free Vinyl Patient Examination Gloves, Clear (non-colored), non sterile are summarized with the following technological characteristics compared to ASTM or equivalent standard.

| Characteristics | Standard | Device performance |
|-----------------------|---|---|
| Dimension | ASTM standard D 5250-06(Reapproved 2011). | Meets |
| Physical Properties | ASTM standard D 5250-06(Reapproved 2011). | Meets |
| Freedom from pinholes | 21 CFR 800.20 | Meets |
| Powder Residual | ASTM standard D 5250-06 (Reapproved 2011).and D6124-06(Reapproved 2011). | Meets <2mg/glove |
| Biocompatibility | Primary Skin Irritation in rabbits ISO 10993-10:2002 /Amd.1:2006 | Passes Not a Primary Skin Irritation |
| | Dermal sensitization in the guinea pig ISO 10993-10: 2002 /Amd.1:2006 | Passes Not a Dermal sensitization |

7.0 Substantial Equivalent Based on Assessment of Non-Clinical Performance Data:

Powder Free Vinyl Patient Examination Gloves, Clear (non-colored), meet requirements per ASTM D5250-06 (Reapproved 2011), per ASTM D6124-06(Reapproved 2011), per 21 CFR 800.20 and ISO 10993-10: 2002/Amd.1:2006.

The performance test data of the non clinical tests that support a determination of substantial equivalent is the same as mentioned immediately above.

8.0 Substantial Equivalent Based on Assessment of Clinical Performance Data:

Clinical data is not needed for gloves or for most devices cleared by the 510(k) process.

9.0 Substantial Equivalence Comparison:

| Features & Description | Predicate Device | Subject Device | Result of Comparison |
|---------------------------------------|---|---|--------------------------|
| Company | Zhang Jia Gang Fengyuan Plastic Product Co.Ltd. | Jiangsu Toptouch Glove Co., Ltd. | -- |
| 510(K) Number | K091663 | -- | |
| Product name | Powder Free Vinyl Patient Examination Gloves, Clear (Non-colored) | Powder Free Vinyl Patient Examination Gloves, Clear (non-colored) | same |
| Product Code | LYZ | LYZ | same |
| Size | Small/ Medium/ Large/X large | Small/ Medium/ Large/X large | same |
| Intend for use | Powder free Vinyl Patient Examination Gloves, Clear(Non-colored)is a disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner. | Powder free Vinyl Patient Examination Gloves, Clear (Non-colored) is a disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner. | Substantially equivalent |
| Device Description and Specifications | Meets ASTM D5250-06 (Reapproved 2011) | Meets ASTM D5250-06 (Reapproved 2011) | Substantially equivalent |
| Dimensions --Length | Meets ASTM D5250 -06 (Reapproved 2011) ≥ 230 mm min | 230mm min for all sizes | Substantially equivalent |
| Dimensions -- Width | Meets ASTM D5250-06 (Reapproved 2011) Small 80-90 mm Medium 90-100mm Large 100-110mm Xlarge 110-120 mm | Small 80-85 mm Medium 95-100mm Large 102-108mm X large 113-118 mm | Substantially equivalent |

| | | | |
|--|--|---|--------------------------|
| Dimensions --Thickness | Meets ASTM D5250-06 (Reapproved 2011) Finger 0.05mm min. Palm 0.08mm min. | Thickness (mm) min. Finger 0.09-0.12 Palm 0.09-0.12 | Substantially equivalent |
| Physical Properties | Meets ASTM D 5250-06 (Reapproved 2011) Before aging/after aging Elongation $\geq 300\%$ Tensile Strength $\geq 14\text{MPa}$ | Before aging/after aging Elongation :390-420% Tensile Strength:15-20 MPa | Substantially equivalent |
| Freedom from Pinholes | Meets <ul style="list-style-type: none"> • 21 CFR 800.20 • ASTM D5250-06 (Reapproved 2011) • ASTM D 5151-06 (Reapproved 2011) | Meets ASTM D5151-06 (Reapproved 2011) Holes at Inspection Level I AQL2.5 | Substantially equivalent |
| Residual Powder | Meets ASTM D 6124-06 (Reapproved 2011) below 2mg of residual powder | Meets ASTM D 6124-06 (Reapproved 2011) Results generated values below 2mg of residual powder | Substantially equivalent |
| Materials used to fabricate the devices | PVC | PVC | Substantially equivalent |
| Dusting or Donning Powder: | PU | PU | Substantially equivalent |
| Dusting or Donning Powder: name | PU | Surface Coating Agent | Substantially equivalent |
| Compare performance data supporting substantial equivalence | Meets ASTM D5151-06 (Reapproved 2011) ASTM D5250-06 (Reapproved 2011) ASTM D6124-06 (Reapproved 2011) | Meets ASTM D5151-06 (Reapproved 2011) ASTM D5250-06 (Reapproved 2011) ASTM D6124-06 (Reapproved 2011) | Substantially equivalent |
| Single Patient Use | Single Patient Use | Single Patient Use | Substantially equivalent |
| Biocompatibility | SKIN IRRITATION DERMAL and SENSITIZATION STUDIES Meets ISO 10993-10:2002/Amd.1:2006 | The test article was a non-irritant and non-sensitizer. SKIN IRRITATION DERMAL and SENSITIZATION STUDIES Meets ISO 10993-10:2002 /Amd.1:2006 | Substantially equivalent |
| Labeling for the legally marketed device to which substantial equivalence is claimed. | -Powder Free -Patient Examination Glove -Single Use Only - Manufactured For: - Lot | -Powder Free -Patient Examination Glove -Single Use Only - Manufactured For: - Lot | Substantially equivalent |

10.0 Substantial Equivalence Comparison:

It can be concluded that the Powder Free Vinyl Patient Examination Gloves, Clear (non-colored) meet the ASTM standard or equivalent standard and FDA requirements for waterleak test on pinhole AQL., meet labeling claims.

It can be concluded that the Powder Free Vinyl Patient Examination Gloves, Clear (non-colored) is as safe, as effective, and performs as well as the predicate device, Powder-Free Vinyl Patient Examination Glove (Non-colored) Zhang Jia Gang Fengyuan Plastic Product Co., Ltd. K091663.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
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November 22, 2013

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C/O Chu Xiaoran
Beijing Easy-Link Company, Limited
Room 1606 Building 1
Jian Xiang Yuan Number 209
Bei Si Huan Zhong Road Haidan District
CHINA 100083

Re: K131826

Trade/Device Name: Powder Free Vinyl Patient Examination Gloves, Clear (non-colored)
Regulation Number: 21 CFR 880.6250
Regulation Name: Patient Examination Glove
Regulatory Class: I
Product Code: LYZ
Dated: October 14, 2013
Received: October 24, 2013

Dear Mr. Xiaoran:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA).

You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

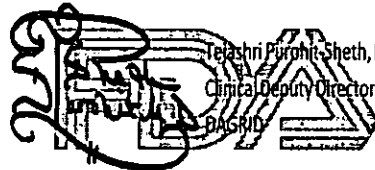
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,


Tejasri Parohit Sheth, M.D.
Clinical Deputy Director
DAGRID
FOR

Erin Keith, M.S.
Division Director, Acting
Division of Anesthesia, General Hospital,
Respiratory, Infection Control, and Dental
Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)
K131826

Device Name
Powder Free Vinyl Patient Examination Gloves, Clear (non-colored)

Indications for Use (Describe)

Powder Free Vinyl Patient Examination Gloves, Clear (non-colored) is a non-sterile disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.

Type of Use (Select one or both, as applicable)

☐ Prescription Use (Part 21 CFR 801 Subpart D)

☒ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

Elizabeth F. Claverie S

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